



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

m4134n

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Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

WARNING LETTER

NOTIFICATION OF USE-PROHIBITED CLASSIFICATION

Via Telefax  
Original via Certified Mail  
Return Receipt Requested

FILE NO.: 00-NWJ-48

18 August 2000

Michael E. Harkins  
Executive Director  
Delaware River and Bay Authority  
I-295 @ Delaware Memorial Bridge  
New Castle, Delaware 19720

Dear Mr. Harkins:

This letter serves as your formal notification that the Food and Drug Administration (FDA) has now classified the food preparation services on the ferry fleet of the Delaware River and Bay Authority as *Use-Prohibited*.

Your classification as *Use-Prohibited* means you should no longer prepare, serve, or sell any food that requires manual manipulation of ingredients, that is time or temperature sensitive, or that might otherwise be affected by the unsanitary conditions observed aboard your vessels.

Three recent inspections of these food preparation services have disclosed numerous violations of the Public Health Services Act (PHS Act) and the Food Drug and Cosmetic Act (FD&C Act). See 42 U.S.C. § 264; 21 U.S.C. § 342(a)(4); 21 CFR Parts 110, 1240 and 1250. Although the August 8-10, 2000 inspection revealed that you have made progress toward complying with these statutes and regulations, the conditions under which food is stored, handled, prepared, and served remain unsanitary.

FDA conducted an inspection of four of the motor vessels in the Cape May Lewes Ferry fleet from August 8-10, 2000. FDA considers a score of 85 or better on the Food Service Establishment Inspection Report, Form FDA 2420, to be a satisfactory rating. The four vessels inspected received the following scores: MV *Cape May*, 63, MV *Henlopen*, 80, MV *Twin Capes*, 82, and MV *Delaware*, 74.

Our June 10-12, 2000 inspection disclosed significant deficiencies in the manner in which food was stored and prepared on these vessels. As a result, our June 28, 2000 Warning Letter classified your food preparation services as *Provisional*. The letter also warned you that a failure to take corrective actions and achieve satisfactory ratings during a subsequent inspection would result in a classification of the food preparation services on the Cape May Lewes Ferries as *Use-Prohibited*.

During the third inspection of August 8-10, 2000, we continued to observe significant deficiencies related to the food preparation services and sanitation. The following are examples of the deficiencies that led to the poor scores on the recent Food Establishment Inspection Reports and resulted in the classification of *Use-Prohibited*. Similar types of deficiencies were also cited during the June 12-14, 2000 and July 10-12, 2000 inspections.

1. Potentially hazardous food was not prepared, stored, displayed, or served at required temperatures. This factor is considered to be critical and could significantly contribute to the potential for foodborne illness. Cooked food should be held at 140°F or above. Our investigators took internal temperatures of cooked food being held for service and found temperatures below the requirement. For example:

Pork Roll -- 106°F and 118°F  
Round Bacon Slices -- 118°F  
French Fries -- 120°F and 138°F

2. Our investigators measured the concentration of quaternary ammonia sanitizing agent in a 3-compartment sink, and found it to be only 50ppm. This concentration is not sufficient to sanitize equipment and utensils. The manufacturer's recommendation for effective sanitizing is a concentration of 100-200ppm.

Additionally, wiping cloths used for sanitizing cutting boards and other food-contact surfaces should be stored in a sanitizing solution that is maintained at the appropriate concentration. Our investigators observed that wiping cloths were not stored in a sanitizing solution.

3. Employees working in direct contact with food or food-contact surfaces were observed using poor hygienic practices. Specifically:

- Our investigators observed a food service employee preparing and handling food with unprotected and/or inadequately protected cuts on his hands.
- Employees working barehanded did not wash their hands after touching non-food contact surfaces and before preparing food. For example, an employee was observed touching non-food contact surfaces and then handling a hamburger bun without washing his/her hands.
- Employees working with gloves did not change their gloves after touching non-food contact surfaces and before preparing food. For example, on two occasions, employees were observed touching non-food contact surfaces and then handling raw produce without changing gloves.

- Employees were not wearing hair restraints in a manner that would prevent contamination of food products.

These poor hygienic practices could significantly contribute to the potential for foodborne illness.

4. The facilities used for food preparation and service aboard the MV *Twin Capes* and the MV *Cape May* were observed to be unsanitary, in that numerous flies were in the food preparation facilities of both ships. The flies were observed landing on food products and utensils.
5. Food-contact surfaces on the four inspected vessels were not clean to sight and touch. Our investigators observed that utensils and equipment were greasy and contained a build-up of dried food-like debris.

In addition, on August 10, 2000, food contact surfaces and utensils aboard the MV *New Jersey* were observed to be greasy and to contain food-like material. The MV *New Jersey* was last in service on August 8, 2000. Food contact surfaces should be cleaned immediately following the day's operations. A Food Service Establishment Inspection Report was not completed for the MV *New Jersey* because it was not operating during the inspection.

6. Cleaned equipment was improperly stored between uses. For example, serving pans were stacked while wet, creating a wet nesting environment that could lead to bacterial growth. Additionally, cleaned utensils were stored directly above a grill, subjecting them to contamination.

As an operator of an interstate conveyance, it is your responsibility to comply with all applicable laws and regulations. The violations outlined in this letter are not intended to be an all-inclusive list of the deficiencies that exist with your food preparation operations.

Due to the seriousness of the deviations listed above, FDA is classifying your food preparation operations as *Use-Prohibited*. Your vessels will retain this classification until FDA conducts a reinspection and the vessels achieve satisfactory ratings. FDA will conduct the reinspection after you have submitted an acceptable Corrective Action Plan (CAP).

The CAP should outline the corrective actions that you have taken, the corrective actions that you plan to take, the manner in which these corrections will be maintained in the future, and the time frames necessary to complete all corrective actions. The CAP should also include a comprehensive training program that will ensure compliance of both management and food service employees. The training program should ensure that food service management personnel are aware of what the FD&C Act, PHS Act, and current regulations require with respect to food sanitation. Management personnel should also demonstrate the ability to supervise employees to ensure compliance during all hours of operation. Your long-term training plan should also include provisions for training seasonal employees in food safety practices prior to their handling of potentially hazardous food.

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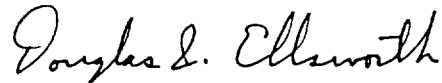
Delaware River and Bay Authority  
Warning Letter/Use-Prohibited Classification

You should notify us within five (5) business days whether you intend to terminate all food preparation on the Cape May Lewes Ferries. If you continue to prepare and serve food while classified as *Use-Prohibited*, FDA will consider taking further action. Such action may include the seizure of all food that is not in compliance with the FD&C Act or an injunction prohibiting the preparation and service of food on your vessels.

We acknowledge receipt of your letter dated August 16, 2000, which was written in response to the Form FDA-483 issued on August 10, 2000. However, the letter indicates that you are still in the process of developing and implementing new procedures, and we are unable to accept this as a CAP.

Please send your initial response and the CAP to the attention of Kirk D. Sooter, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Boulevard, 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054.

Sincerely,



Douglas I. Ellsworth  
District Director  
New Jersey District

cc: Jeffrey D. Lewis, Chief Operating Officer  
Delaware River and Bay Authority

Commanding Officer  
Marine Safety Office  
U.S. Coast Guard  
Philadelphia, Pennsylvania